Appln No.: 09/824,587
Amendment Dated: May 18, 2005

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1.-20. (canceled)

21. (currently amended) A method for differentiating between a first state and a second state of an analyte that exists in a plurality of different forms, wherein in the first state the analyte is present in a first set of ~~iso~~forms and in the second state the analyte is present is a second set of ~~iso~~forms, wherein the first set of ~~iso~~forms differs from the second set of ~~iso~~forms as a result of containing different forms of the analyte in different relative amounts, said method comprising the steps of:

(a) obtaining first and second assay samples containing the analyte, said first and second assay samples being either aliquots of a single sample or contemporaneous samples from the same source;

(b) performing a first specific binding assay on the first assay sample by reacting the first assay sample with a first binding agent to form a first binding agent/analyte complex, and then subsequently reacting the first binding agent/analyte complex with a second binding agent to form a first binding agent/analyte/second binding agent complex;

(c) performing a second specific binding assay on the second assay sample by reacting the second assay sample substantially simultaneously with the first binding agent and the second binding agent to form a first binding agent/analyte/second binding agent complex;

(d) determining the amount of first binding agent/analyte/second binding agent complex formed in the first specific binding assay and the second specific binding assay; and

(e) comparing the amount of first binding agent/analyte/second binding agent complex formed in the first specific binding assay and the second specific binding assay, wherein at least one of the first and second binding agents has a different specificity for the forms of the analyte, whereby the amount of first binding agent/analyte/second binding agent complex formed in the first and second specific binding assays differs depending on the state of the analyte in the sample, said comparison thereby providing a differentiation between the first state and the second state of the analyte.

22. (previously presented) The method of claim 21, wherein each of the first and second binding reagents have a different specificity for the forms of the analyte.

23. (previously presented) The method of claim 22, further comprising the step of calculating a combined test result, expressed as a ratio of the amounts of first binding agent/analyte/second binding agent complex formed in the first and second specific binding assays.

24. (previously presented) The method of claim 23, further comprising the step of comparing the combined test result to a standard ratio representative of the first or second state to determine in which state the sample exists.

25. (previously presented) The method of claim 24, wherein the analyte is a gonadotrophin.

26. (previously presented) The method of claim 25, wherein the analyte is follicle stimulating hormone.

27. (previously presented) The method of claim 22, wherein the analyte is a gonadotrophin.

28. (previously presented) The method of claim 27, wherein the analyte is follicle stimulating hormone.

29. (previously presented) The method of claim 21, further comprising the step of calculating a combined test result, expressed as a ratio of the amounts of first binding agent/analyte/second binding agent complex formed in the first and second specific binding assays.

30. (previously presented) The method of claim 29, further comprising the step of comparing the combined test result to a standard ratio representative of the first or second state to determine in which state the sample exists.

31. (previously presented) The method of claim 30, wherein the analyte is a gonadotrophin.

32. (previously presented) The method of claim 31, wherein the analyte is follicle stimulating hormone.

33. (previously presented) The method of claim 21, wherein the analyte is a gonadotrophin.

34. (previously presented) The method of claim 33, wherein the analyte is follicle stimulating hormone.

35. (previously presented) The method according to claim 21, wherein the first and second specific binding agents are antibodies.

36. (previously presented) The method according to claim 35, wherein each binding agent is a monoclonal antibody.

37. (previously presented) The method of claim 35, wherein each of the first and second binding reagents have a different specificity for the forms of the analyte.

38. (previously presented) The method of claim 37, further comprising the step of calculating a combined test result, expressed as a ratio of the amounts of first binding agent/analyte/second binding agent complex formed in the first and second specific binding assays.

39. (previously presented) The method of claim 38, further comprising the step of comparing the combined test result to a standard ratio representative of the first or second state to determine in which state the sample exists.

40. (previously presented) The method of claim 39, wherein the analyte is a gonadotrophin.

41. (previously presented) The method of claim 40, wherein the analyte is follicle stimulating hormone.

42. (previously presented) The method of claim 35, wherein the analyte is a gonadotrophin.

43. (previously presented) The method of claim 42, wherein the analyte is follicle stimulating hormone.

44. (previously presented) The method of claim 21, wherein in the first specific binding assay, the sample is incubated with a solid phase on which is immobilized the first binding agent, and thereafter, following removal of unbound analyte, the solid phase is incubated with the second binding agent.

45. (previously presented) The method of claim 44, wherein in the second specific binding assay, the sample is substantially simultaneously incubated with a solid phase to which the first binding reagent is immobilized and with the second binding agent in solution or suspension.

46. (previously presented) The method of claim 21, wherein in the second specific binding assay, the sample is substantially simultaneously incubated with a solid phase to which the first binding reagent is immobilized and with the second binding agent in solution or suspension.

47. (previously presented) The method of claim 21, wherein the first or second binding agent is labeled with a label selected from the group consisting of enzymes, fluorescent labels, radiolabels and direct particulate labels.

48. (previously presented) The method of claim 21, wherein one of the first or second binding agents comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032004.

49. (previously presented) The method of claim 21, wherein one of the first or second binding agents comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032005.

50. (previously presented) The method of claim 21, wherein one of the first or second binding agents comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032004 and the other comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032005.

51. (withdrawn) A method for evaluating first and second assay samples obtained from a female subject to determine if the subject is in first state in which the subject is in a present or impending fertile condition or a second state in which the subject is in a present or impending infertile condition, comprising evaluating the first and second assay samples in accordance with the method of claim 21, wherein the difference between the amounts of first binding agent/analyte/second binding agent complex formed in the first and second specific binding assays is indicative of the state of fertility of the female subject.

52. (withdrawn) The method of claim 51, wherein one of the first or second binding agents comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032004.

53. (withdrawn) The method of claim 51, wherein one of the first or second binding agents comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032005.

54. (withdrawn) The method of claim 51, wherein one of the first or second binding agents comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032004 and the other comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032005.